P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

zimmer

Summary of Safety and Effectiveness

MAR 4 2013

Sponsor:

Zimmer, GmbH
Sulzer Allee 8
Winterthur
CH-8404
Switzerland

Contact Person:

Karen O'Leary
Senior Specialist, Regulatory Affairs
Telephone: (574) 371-8515
Fax: (574) 372-4605

Date:

01 November 2012

Trade Name:

Avenir® Müller Stem

Product Code / Device:

LZO – Prosthesis, hip, semi-constrained, metal/ceramic/polymer, cemented or non-porous, uncemented

LWJ - Prosthesis, hip, semi-constrained, metal/polymer, uncemented

MEH - Prosthesis, hip, semi-constrained, uncemented, metal/polymer, non-porous, calcium-phosphate

KWZ - prosthesis, hip, constrained, cemented or uncemented, metal/polymer

KWY - prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented

Regulation Number / Description:

21 CFR § 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

21 CFR § 888.3360 Hip joint femoral (hemi-hip) metallic cemented or uncemented prosthesis.

21 CFR § 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis.

21 CFR § 888.3310 Hip joint metal/polymer constrained cemented or uncemented prosthesis.

21 CFR § 888.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis.

Predicate Device:

Corail AMT™ Hip Prosthesis, manufactured by DePuy Orthopaedics Inc, K042992, cleared February 11, 2005

Zimmer® *Porolock* MIS Stem, manufactured by Zimmer Inc, K071723, cleared March 03, 2008

Device Description:

The *Avenir*® Müller stem is a titanium alloy femoral stem designed to replace the proximal femur in total or hemi-hip arthroplasty. Except for the polished neck area, the surface of the stem is coated with air plasma sprayed (APS)-Ti and oversprayed by a hydroxyapatite coating. It is a wedge-shaped, collarless design with a proximal-to-distal taper. The stem is available as both a lateralized and standard version.

Intended Use:

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemi-arthroplasty or total hip replacement (THR).
- Acute traumatic fracture of the femoral head or neck
- Avascular necrosis of the femoral head.

Avenir Müller Stems are for cementless use only.

Comparison to Predicate Device:

The *Avenir*® Müller Stem is similar or identical in intended use, materials, sterility and performance characteristics to the predicate device(s).

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical (lab) performance testing demonstrate the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing/analysis included: Proximal Stem Fatigue Test, Distal Stem Fatigue, Pull-off Strength Testing, Hydroxyapatite Coating Characterization Testing, Plasma Spray Coating Characterization Testing, Hydroxyapatite Coating Characterization Evaluation of Real Aged Avenir Stems, Burst Strength Testing and Range of Motion analysis.

Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 4, 2013

Zimmer, GmbH
% Zimmer Incorporated
Ms. Karen O'Leary
Senior Specialist, Regulatory Affairs
Sulzer Allee 8
Winterthur CH-8404
Switzerland

Re: K123392
Trade/Device Name: Avenir® Müller Stem
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, LWJ, MEH, KWZ, KWY
Dated: January 29, 2013
Received: February 1, 2013

Dear Ms. O'Leary:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin D. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123392

Device Name:

Avenir® Müller Stem

Indications for Use:

- Advanced wear of the joint due to degenerative, post-traumatic or rheumatic diseases.
- Failed previous hip surgery including joint reconstruction (osteotomy), arthrodesis, hemi-arthroplasty or total hip replacement (THR).
- Acute traumatic fracture of the femoral head or neck.
- Avascular necrosis of the femoral head.

Avenir Müller Stems are for cementless use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices